

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

This application pertains to novel solid lipid particles of bioactive agents and methods for the manufacture and use thereof.

Formal Matters

Applicants have amended claims 16, 26 and 40 to remove the dependence on claim 1.

Applicants have also added new claims 41-45, which recite the limitations of original claims 5-8 and 10, respectively.

Applicants respectfully submit that the amendments to the claims do not introduce new matter. An early notice to that effect is earnestly solicited.

As a result of the amendment, claims 1-45 are now pending.

Claims 1-15 and 37-39 are withdrawn from consideration, while Applicants still traverse the election of Group II and V.

Reconsideration and withdrawal of the restriction requirement is respectfully requested for the reasons already stated in the response to the restriction requirement.

In case the Examiner still does not withdraw the restriction requirement, Applicants respectfully request that the non-elected subject matter be rejoined with the elected subject matter upon allowance of the elected subject matter.

The description stands objected to because it does not recite the foreign priority in the first line of the specification. In response, Applicants have amended the first page of the specification to refer to the German priority application. It is believed that this amendment obviates the objection, and the objection should now be withdrawn.

Rejections under 35 USC § 112

Claims 16-36 and 40 stand rejected under 35 USC 112 first paragraph as failing to comply with the written description requirement. In response, Applicants respectfully submit that this rejection is untenable and respectfully request that it be reconsidered and withdrawn.

The Examiner calls on Applicants to limit the “dispersant,” “additives” and “coating materials” in the claims to a list of specific disclosed components.

Claims 16 and 40 recite “dispersant,” “additives” and “coating materials, which the Examiner contends to be subject matter which is not described in the specification in such a way as to reasonably convey knowledge to one skilled in the relevant art that the inventor had possession of it at the time the instant application was filed. Therefore the Examiner requests recitation of specific components in the claims. However, Applicants respectfully decline such request.

In particular, Applicants respectfully submit that each of these terms is adequately defined in the specification and the Examiner has not shown the criticality of the selection or any other reason that would justify a requirement that Applicants limit the claims to lists of specific disclosed components. To the contrary, these terms are used and defined in the instant specification in exactly the same scope with which they are claimed and, moreover, numerous specific examples are given of each. A person having ordinary skill in the art has no difficulty understanding that Applicants had possession of the full scope of these terms by the filing date or, for that matter, in practicing the full scope of the invention. Therefore, Applicants respectfully submit that the Examiner’s call for narrowing the claims is unjustified and should be reconsidered and withdrawn.

In further support of the foregoing, Applicants refer the Examiner to numbered paragraphs of the published application, which is Publication No. US 2004/0076670 A1.

Concerning “dispersant” the Examiner is kindly requested to refer to the written description on page 3, paragraph [0049] to page 4, paragraph [0051], wherein a detailed description of “dispersants” is given along with specific embodiments of such. Their nature of being surface-active is disclosed as well (see page 4, paragraph [0051], lines 4-5). Use of “dispersants” is supported by Examples 1 (paragraph

[0180], “phosphoric acid mono-/diester mixture of a tristyrolphenol ethoxylate containing an average of 16 ethylene oxide units”) and 2 (paragraph [0185], “Tween 80”). Hence one skilled in the art understands that Applicants had possession of “dispersants” generally and is, moreover, certainly able to reproduce Applicants’ invention with regard to the full scope of “dispersants.”

Concerning “additives,” the Examiner is kindly requested to refer to page 4, paragraph [0057], wherein a detailed description of “additives” is given. Furthermore the definition of “additives” on page 4 paragraph [0057] contains examples of descriptive substance classes found suitable as “additives” in Applicants’ invention, namely “penetrants, defoamers, low-temperature stabilizers, preservatives, dyes, redispersants, disintegrants, inert fillers and film formers.” Clearly, one of ordinary skill in the art understands that Applicants had possession of “additives” generally and is, moreover, able to reproduce Applicants’ invention with regard to the full scope of “additives.”

Similarly, concerning “coating materials,” the Examiner is kindly requested to refer to page 4, paragraph [0052] to paragraph [0056], wherein specific embodiments of “coating materials” are given. “Coating material” is furthermore a word of descriptive nature, indicating one skilled in the art which components to use to conduct Applicants’ invention. Use of “coating material” is supported by Examples 1 (paragraph [0182], “mixed with 1.2 liters of a 25% strength by weight solution of polyvinyl alcohol (Mowiol®3-83 Clariant)” in water) and 2 (paragraph [0186], “21.6 parts per weight of capsule material (25 % strength by weight solution of polyvinyl alcohol Mowiol®3-83 from Clariant in water”). Again, one of ordinary skill in the art understands that Applicants had possession of “coating materials” generally and is, moreover, able to reproduce Applicants’ invention with regard to the full scope of “coating materials.”

Accordingly the rejected claims do not contain subject matter which was not detailed in the specification sufficient to satisfy the written description.

Hence the rejection of Claims 16 and 40 under 35 USC § 112 first paragraph should now be withdrawn. As claims 17-36 are dependent on Claim 16, the rejection of such under 35 USC § 112 first paragraph should be withdrawn as well.

Claims 16 and 40 stand rejected under 35 USC § 112 second paragraph as being indefinite, due to the use of the term “optionally.” In response, Applicants respectfully submit that the term “optionally” used in the present context is most certainly definite. In this regard, Applicants refer the Examiner to MPEP § 2173.05(h)(III), which, in turn refers to the decision in *Ex parte Cordova*, 10 USPQ2d 1949 (BPAI 1989). As set forth in the MPEP section, “[i]n *Ex parte Cordova*, * * * the language ‘containing A, B, and optionally C’ was considered to be acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim.” Indeed, there are only two such alternatives: (1) containing A + B + C or (2) containing A + B without C. Applicants’ use of “optionally” here is essentially the same as in the *Cordova* case and, therefore, must be accepted for the same reasons.

According to the Examiner, Applicants’ use of the term “optionally” renders the claim indefinite because “[i]t is not clear whether the limitation is really the limitation.” Applicants have no idea what this statement means and respectfully request that the Examiner clarify the statement if this rejection is somehow maintained. Applicants respectfully submit, particularly in view of the explanation given above, that Applicants’ use of the term “optionally” in this instance is perfectly clear. In each instance, it means additives C) are either used or they are not used.

Hence the rejection of claims 16 and 40 under 35 USC § 112 second paragraph should now be withdrawn.

Rejection under 35 USC § 103

Claims 16-36 and 40 stand rejected under 35 U.S.C. 103(a) as being obvious over Westesen et al. (“Westesen”), US 5,885,486, in view of Timothy et al. (“Timothy”), *Biotechnol. Prog.*, 16: 402-407 (2000). In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner contends that the sole difference between Westesen and the rejected claims is that Westesen does not disclose addition of compressible fluid in the supercritical state under pressure to the

suspension.

Applicants respectfully point out that this is not the only difference between the rejected claims and Westesen. Westesen additionally fails to disclose the requirement of the instant claims of “suspending at least one active substance A), which is solid at room temperature (...) in an aqueous phase.”

Westesen discloses a method to form solid lipid particles (SLP's) by melting solid lipids (Col. 11, line 6) and dispersing the melt into the dispersion medium to form an emulsion (col 11, lines 25-30), while the melt may contain bioactive agents in molten, dissolved, solubilized or dispersed form (col. 11, lines 16-20). Hence, if the bioactive agents are dispersed, they are dispersed in the molten lipid and therefore intrinsically an emulsion does prevail. Existence of “particulate contaminations (...) which could lead to heterogeneous nucleation should be avoided (...) prior to cooling” (col. 11, lines 39-43).

Furthermore, Westesen discloses melting meltable bioactive agents and forming dispersions of such by a process similar to the forming SLP's (col. 14, lines 19-26). Hence the bioactive agents are not suspended in an aqueous phase, but melted and emulsified in a heated dispersing medium.

Accordingly, the disclosure of Westesen pertains to a method of melting and emulsification in a pre-heated dispersion medium as an inevitable step. Existence of suspensions shall even be avoided during the process before the cooling.

Applicants' process additionally seeks to minimize an emulsified state of the system to a maximum extend of a few milliseconds (see paragraph [0132], last sentence) and uses a process defined by the existence of suspended particles even before passing the short emulsion step.

The disclosure of Timothy does not help to overcome these general discrepancies between Westesen and Applicants' claimed process of Claims 16-36 and 40.

From the foregoing, it is clear that Applicants' claims are not obvious over Westesen in view of Timothy and the rejection of claims 16-36 and 40 under 35 U.S.C. 103(a) as obvious over Westesen in view of Timothy should now be withdrawn.

In view of the present amendments and remarks it is believed that claims 16-36 and 41-45 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

Early and favorable action is earnestly solicited.

Respectfully submitted,
NORRIS McLAUGHLIN & MARCUS, P.A.

By //Kurt G. Briscoe//
Kurt G. Briscoe
Attorney for Applicant(s)
Reg. No. 33,141
875 Third Avenue
18TH Floor
New York, New York 10022
Phone: (212) 808-0700
Fax: (212) 808-0844